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Dec  
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICATION OF: Clive Patience

SERIAL NO: 09/766,154

Art Unit: 1632

FILED: 19 January 2001

Examiner: Wehbe, A. M.

FOR: SWINE DEFECTIVE FOR TRANSMISSION OF PORCINE  
ENDOGENOUS RETROVIRUS AND USES THEREOF

DOCKET NO: 61750-311

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

MAIL STOP: AF

DECLARATION OF DR. CLIVE PATIENCE UNDER 37 C.F.R. 1.132

Sir:

Dr. Clive Patience states as follows:

1. I am the inventor of the subject application.
2. I hold a Ph.D. in microbiology from University of London, UK.
3. I have read the above patent application and the Office Action pending in the above-referenced application.

4. As part of my research I have been involved in the breeding animals, including swine, and examination of said animals for the transmission of endogenous retroviruses from cells of such animals to cells from human beings.

5. As a result of my work with breeding animals that can transmit endogenous retroviruses to human beings, data shows that such transmission has occurred from cells of swine, which is of the D/D haplotype to cultured human cells.

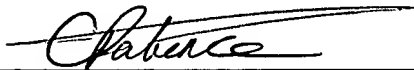
6. Specifically, we investigated the PERV transmission characteristics of the inbred herd of miniature swine using *in vitro* co-culture assays of porcine peripheral blood mononuclear cells (PBMC) with the human 293 cell line (Oldmixon, B.A., *et al*, Porcine endogenous retrovirus transmission characteristics of an inbred herd of miniature swine. J Virol 76:3045-8). As shown in Appendix 1, transmitting animals could be identified within all haplotypes of miniature swine including the SLA<sup>D/D</sup> haplotype.

7. These results indicate that the inability to transmit PERV to human cells is not an intrinsic property of the SLA<sup>D/D</sup> haplotype animals. Conversely, selective breeding procedures, such as those disclosed in the above-referenced patent application will be required to maintain human-tropic PERV-free animals.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine, or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may

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jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

A handwritten signature in cursive script, appearing to read "Clive Patience", written over a horizontal line.

Clive Patience  
Date: 6/23/03

## Appendix 1

### Expanded PERV Transmission Analysis of the Miniature Swine Herd

Animal #	Haplotype	293	
		Pos	Neg
10715	D/D	0	3
12177	D/D	0	1
12521	D/D	0	2
12525	D/D	0	1
13452	D/D	0	1
13517	D/D	1	0
13519	D/D	4	0
13606	D/D	0	1
13609	D/D	0	1
13026	D/D	1	0
13680	D/D	0	1
13681	D/D	1	0
13688	D/D	0	1
13730	D/D	0	1
13741	D/D	0	2
13766	D/D	0	1
13862	D/D	2	0
13864	D/D	0	2
13867	D/D	0	4
13910	D/D	6	0
14062	D/D	0	1
14063	D/D	0	1
14064	D/D	1	0
14065	D/D	2	0
14068	D/D	0	1
14092	D/D	0	1
14093	D/D	0	1
14094	D/D	0	1
14111	D/D	2	0
14166	D/D	0	1
14231	D/D	0	1
14257	D/D	0	1
14259	D/D	0	1
14271	D/D	0	1
14335	D/D	0	2
14401	D/D	0	1
14402	D/D	0	1

14404	D/D	0	1
14565	D/D	0	1
14645	D/D	0	1
14646	D/D	0	1
14647	D/D	0	1
14649	D/D	0	1
14662**	D/D	1	0
14663	D/D	0	1
14664	D/D	0	1
14665	D/D	3	1
14666	D/D	0	5
14672	D/D	0	1
14678	D/D	0	1
14754	D/D	0	1
14755	D/D	0	1
14756	D/D	0	1
14757	D/D	0	1
14758	D/D	0	1
14759	D/D	0	1
14771	D/D	0	3
14772	D/D	0	3
14773	D/D	0	1
14774	D/D	0	3
14775	D/D	0	1
14776	D/D	0	1
14777	D/D	0	1
14778	D/D	0	1
14779	D/D	0	1
14780	D/D	0	1
14781	D/D	0	1
15150	D/D	2	0
15151	D/D	0	2

10666	A/A	0	1
12319	A/A	1	0
13972	A/A	0	1
14102	A/A	0	1
14428	A/A	0	1
14439	A/A	0	1

11932	C/C	0	1
12182	C/C	1	0
14109	C/C	1	0
14351	C/C	0	1
14365	C/C	0	1

14486	C/C	0	1
15101	C/C	0	4

12030	H/H	0	3
12109	H/H	3	0
14147	H/H	0	1
14148	H/H	0	1

10285	G/G	2	0
12190	G/G	0	4
12408	G/G	0	1
12429	G/G	0	1
12550	G/G	0	4
13162	G/G	0	1
13414	G/G	0	1
13586	G/G	0	1
13587	G/G	0	1
13670	G/G	0	1

11619	K/K	2	0
13752	K/K	0	3
13760	K/K	0	1
13877	K/K	0	1

10707	A/D	3	0
12886	A/D	1	2
13999	A/D	0	2
14865	A/D	1	2
14868	A/D	1	2

13653	C/D	4	0
13937	C/D	0	1
12928	C/D	0	1
15149	C/D	1	1

14672	A/C	0	2
14678	A/C	0	1